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Subpart A—General Provisions**§ 106.1 Status and applicability of the quality control procedures regulation.**

(a) The criteria set forth in §§ 106.20, 106.25, 106.30, 106.90, and 106.100 shall apply in determining whether an infant formula meets the safety, quality, and nutrient requirements of section 412 of the act and the requirements of regulations promulgated under section 412(a)(2) of the act.

(b) The failure to comply with any regulation set forth in §§ 106.20, 106.25, 106.30, 106.90, and 106.100 applicable to the manufacturing, processing, and packaging of an infant formula shall render such formula adulterated under section 412(a)(1)(C) of the act.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 106.3 Definitions.

The definitions and interpretations contained in section 201 of the act are applicable to such terms when used in this part. The following definitions shall also apply:

(a) *Indicator nutrient.* An indicator nutrient is a nutrient whose concentration is measured during the manufacture of an infant formula to confirm complete addition and/or uniform distribution of a premix or other substance of which the indicator nutrient is a part.

(b) *In-process batch.* An in-process batch is a combination of ingredients at any point in the manufacturing process before packaging.

(c) *Manufacturer.* A manufacturer is a person who prepares, reconstitutes, or otherwise changes the physical or chemical characteristics of an infant formula and/or packages the product in a container for distribution.

(d) *Nutrient.* A nutrient is any vitamin, mineral, or other substance required in accordance with the table set out in section 412(g) of the act or by regulations promulgated under section 412(a)(2)(A) of the act.

(e) *Nutrient premix.* A nutrient premix is a combination of ingredients containing two or more nutrients. A nutrient premix either may be received from a supplier or be prepared by an infant formula manufacturer.

Subpart B—Quality Control Procedures for Assuring Nutrient Content of Infant Formulas**§ 106.20 Ingredient control.**

(a) Except as provided in § 106.20(b), no analysis before use in manufacturing is needed for ingredients that are generally stable in shipping and storage, and that either are received under a supplier's guarantee or certification that the mixture has been analyzed as to nutrient composition or are labeled as having nutrient compositions complying with specifications in the U.S. Pharmacopeia, the National Formulary, the Food Chemicals Codex, or other similar recognized standards.

(b) Unless each batch of finished product is analyzed as specified in § 106.30(b)(1) before release of product